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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,869	12/03/2001	Orest W. Blaschuk	100086.407C7	1299

500 7590 09/09/2003

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EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	4

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,869	BLASCHUK ET AL.	
	Examin r	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,13,14,63-66 and 105-117* is/are pending in the application.

4a) Of the above claim(s) *2-4,13,14 and 63-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-8 and 105-117* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9, 10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Applicant's election of Group I, claims 1-8, 13-14, 63-66, and 105-117, and of SEQ ID NO: 910 in Paper No. 13, filed 6/30/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant is reminded that the requirement for election of a single sequence set forth in the restriction requirement of 4/30/03 was a RESTRICTION requirement. It is noted that the examiner explicitly stated in the restriction requirement that the claims do not recite proper genus/species situation and that the examiner would consider examining more than a single sequence (i.e. would consider a genus/species "type" of examination) if a genus with a *completely defined core structure* were identified which did not require an undue burden of search. In the response filed 6/3/03, applicant merely refers to the elected SEQ ID NO: as a "species" but does not define any particular "genus" with a defined core structure to which this sequence belongs. In the absence of any definition of a core structure, and in the absence of arguments with regard to lack of a proper genus/species situation in the claims, the election of SEQ ID NO: 910 is regarded as a response to the restriction requirement. The restriction requirement also explicitly stated that "Examination will be restricted only to the elected sequences." Only those claims which specifically recite or "read on" SEQ ID NO: 910 are considered elected. SEQ ID NO: 3 does not appear to comprise either the entirety

of elected SEQ ID NO: 910 nor the tripeptide "core" (i.e. DAE) of elected SEQ ID NO: 910, therefore claims reciting SEQ ID NO: 3 are considered nonelected.

Claims 2-4, 13-24, and 63-66 and all SEQ ID NO's other than SEQ ID NO: 910 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected sequences, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.

An action on the merits of claims 1, 5-8, and 105-117, as they read on elected SEQ ID NO: 910, follows.

Information Disclosure Statement

The IDSs filed 2/11/02 and 11/7/02 have been considered.

Specification

The amendment filed 5/2/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the incorporation by reference of the priority documents on page 1 of the specification is new matter. The documents were not incorporated by reference in the originally filed disclosure. It is noted that while the instant specification is a continuation and CIP of the priority applications, the disclosures are not necessarily identical, as the priority applications may have been amended.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 101

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, as set forth in MPEP 2107.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1, 5-8 and 105-117 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

The specification does not assert any particular utility for the claimed invention. The specification discloses that the inventive peptides are modulators of nonclassical or atypical cadherins and implies that the inventive modulators may be used to further investigate nonclassical cadherin function (p. 4). A "use" to do further research is not considered a specific, substantial and credible utility under 35 USC 101. The specification, on page 3, discloses that OB-cadherin may mediate the interaction between malignant cancer cells and other cell types. It is noted that this is a postulated function for a single atypical cadherin. The specification specifically admits, on page 3, lines 14-15, that "functions mediated by atypical cadherins may be diverse." As the functions of atypical cadherins is admitted to be diverse, mere identification as one of the family of atypical cadherins does not impute a particular function or activity to that member. One killed in the art would not know what the utility of a member of the family is simply by identifying the protein as a member of the family, therefore atypical cadherins do not have a specific, substantial and credible utility based on their identification as members of the family. The utility of a modulator of a protein is based on the utility of the protein modulated, wherein no specific protein is identified. As the

claims do not recite any particular nonclassical cadherin , the utility of a modulator thereof is based on the utility of nonclassical cadherins. As set forth above, members of the family of nonclassical cadherins do not appear to have a specific, substantial and credible utility, therefore modulators of nonclassical cadherins do not have a specific, substantial and credible utility.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

Claims 1, 5-8, and 105-107 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-8 and 105-117 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an ENABLEMENT rejection.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

A "modulating agent" comprising SEQ ID NO: 910 is not enabled because neither the specification nor the prior art teach that a peptide or protein comprising SEQ ID NO: 910 is known to modulate anything. It is noted that the claims do not limit WHAT is to be modulated. The specification teaches generally that all of the inventive sequence are modulators of nonclassical cadherins (pp. 3-4), and specifically teaches that cadherin-5 CAR (cell adhesion recognition) sequences may include the tripeptide DAE, on page 32. On page 48, the specification discloses that cadherin-5 CAR sequences may be cyclized, and specifically discloses SEQ ID NO: 910. In Example 3, on pages 146-147, the specification provides evidence that a non-cyclized cadhesion-5 modulating agent, SEQ ID NO: 64, interrupts cell adhesion mediated by a cadherin. It is noted that while SEQ ID NO: 64 comprises the tripeptide "DAE", also comprised within SEQ ID NO: 910. SEQ ID NO: 64 is longer than SEQ ID NO: 910 and is not a cyclic peptide. Further, the Example shows result for only a single peptide out of the many disclosed as being cadhesion-5 "modulators". Nowhere does the specification teach that the sequence DAE, alone, is capable of modulating anything, nor that any cyclized peptide is known to act generally as a modulator, nor specifically as a cadherin modulator. The specification does not provide sufficient evidence or other type of disclosure to allow one of skill in the art ascertain whether all of the members disclosed as "cadherin-5" modulators would reasonably be expected to modulate cadherins; e.g. by showing that

all or a majority of peptides with a particular motif display modulating activity. Although the sequences disclosed as cadherin-5 CAR sequences MAY be expected to recognize a cadherin, it is not known whether they would all bind to the cadherin, nor if they bind, what the result would be expected to be. It is well known in the art that molecules may bind to a protein without overtly disturbing its activity, or (for a multi-function protein) may affect one function without affecting another, may act as an inhibitor, may act as an activator, etc. It is not known or disclosed whether the "modulators" listed as cadherin-5 sequences, if they do indeed modulate a cadherin, would be expected to have the same effect on a cadherin. The specification does not disclose whether SEQ ID NO: 910, specifically, whether as a linear or cyclized version, is known to modulate anything, particularly a nonclassical cadherin.

The state of the prior art is such that proteins/peptides comprising SEQ ID NO: 910 are known in the art. The prior art of ROEBROEK et al. (JBC (1992) vol. 267, no. 4, pp. 17208-17215) teaches a subtilisin-type protein from Drosophila comprising SEQ ID NO: 910 (residues 968-972) on page 17210, Figure 2. The prior art of CILNIS et al. (Virology (1996) vol. 218, pages 343-351) teaches a variety of viral proteins comprising SEQ ID NO: 910 (residues 285-289) in Figure 1 on page 347. However, the prior art does not teach that these sequences, or any portion thereof, are known to be modulators. The fact that proteins are known in the art which comprise SEQ ID NO: 910 and are NOT known to be modulators indicates a high level of uncertainty in the art as to whether "any" peptide or protein comprising SEQ ID NO: 910 would be reasonably expected to be a modulator.

In order for one skilled in the art to determine if SEQ ID NO: 910 is a modulator, one must first choose an agent (protein?) to be modulated. One must then determine a system for testing modulation, and control conditions such that one would be able to detect modulation. One would then have to actually test whether SEQ ID NO: 910 has any modulatory activity in such a system. AS set forth above, the specification does provide some guidance in the form of a working example for how to test for modulation of a nonclassical cadherin. The claims are not so limited. Further, even using the assay disclosed in Example 3, one skilled in the art would still have to test whether SEQ ID NO: 910 indeed has modulatory activity. The level of skill in the art is acknowledged to be high; however, given the lack of teaching in the instant specification for whether SEQ ID NO: 910 is known to modulate anything, and the high degree of uncertainty indicated by the teachings of the prior art, it would require undue experimentation by one skilled in the art to determine whether, or if, SEQ ID NO: 910 is a modulator. One skilled in the art would therefore not know how use SEQ ID NO: 910 as claimed.

Claim Rejections - 35 USC § 102

Examiner's note: The examiner interprets "contains", recited in the claims, to be open claim language, equivalent to -comprises--.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by ROEBROEK et al. (JBC (1992) vol. 267, no. 4, pp. 17208-17215)

REOBROEK teaches a subtilisin-type protein from Drosophila which is at least 3-16 amino acids in length and comprises residues 968-972, which are identical to SEQ ID NO: 910 (page 17210, Figure 2), thereby anticipating claim 1.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by CILNIS et al. (Virology (1996) vol. 218, pages 343-351).

CILNIS teaches a variety of viral proteins, each at least 16 amino acids in length, comprising residues 285-289, which are identical to SEQ ID NO: 910 (Figure 1 on page 347), thereby anticipating claim 1.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER

mam